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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/623,602 09/05/00 CARLSSON

A 13454NP

EXAMINER

HM12/1003

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ART UNIT

PAPER NUMBER

1616

DATE MAILED:

10/03/01

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

<b>Office Action Summary</b>	<b>Application No.</b> 09/623,602	<b>Applicant(s)</b> CARLSSON ET AL.	
	<b>Examiner</b> Sharmila S. Gollamudi	<b>Art Unit</b> 1616	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 05 September 2000.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. § 119**

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

**Attachment(s)**

- |   |  |
|---|--|
| 15) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                  | 18) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 16) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                         | 19) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 17) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>4</u> . | 20) <input type="checkbox"/> Other: _____                                    |

### **DETAILED ACTION**

Preliminary amendments are acknowledged.

Claims 1-12 are included in the prosecution of this application.

#### ***Claim Objections***

The abstract is required to be on a separate page with the heading "Abstract".

Appropriate correction is required.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, "oily material" and "type" is indefinite. What do these materials included? In claims 4-6 "other" is indefinite, not conveying a specific claimed component.

Claim 1 appears to include an active agent in the composition; the dependent claim 8 recites the percentages of components of claim 1 but does not recite any active agent amounts.

Claim 9 the phrase "especially" is indefinite language because it is unclear whether the limitation.

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Claims 1-12 provide for the use of an emulsion, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 1-12 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

### ***Claim Rejections - 35 USC § 102***

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-7, and 9-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Carlsson et al (WO 95/20943).

Carlsson et al discloses a topical oil-in water emulsion containing galactolipids in the instantly claimed amounts. The galactolipids are from oats (pg. 7). The composition further contains digalactosyldiaacylglycerol (examples and claims). Although the reference does not implicitly state that the composition is a lotion, since the reference teaches topical application and since the oil-in-water formulation taught is a liquid, lotion is implicit.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Carlsson et al cited above.

As set forth above Carlsson et al teach the instantly claimed composition for topical application and the preparations contain dermatological drugs (page 5, 3rd paragraph).

The reference does not explicitly teach the forms of topical application such as lotions, creams, etc. Further, the reference does not teach the specific dermatological agents.

It is deemed obvious to one of ordinary skill in the art to choose an appropriate form of the composition with the expectation of obtaining the best possible results. It is also to one of ordinary skill in the art at the time the invention was made to incorporate the desired active agents such as steroids, anti-dermatitis agents and anti-psoriatic agents known if inflammation, dermatitis and psoriasis are the conditions to be treated.

Claims 10-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Carlsson et al cited above in combination with Yamada et al (5,885,978).

Carlsson et al teach a topical oil-in-water emulsion containing galactolipids as set forth above. Further, Carlsson et al teach the incorporation of dermatologic agents.

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The reference does not teach the incorporation of instantly claimed steroid.

Yamada et al teach that steroidal drugs are useful in the treatment of atopic dermatitis. The compositions may be in the form of emulsions (note the abstract, col. 3, lines 5-15 and Tables).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Carlsson et al and Yamada et al since Carlsson et al teach the use of dermatological agents in the emulsion and Yamada et al teach that steroids in emulsion form are routinely used for the treatment of these inflammation. Alternately, the use of the emulsions of Carlsson et al in the teachings of Yamada et al would have been obvious to one of ordinary skill in the art since Carlsson et al teach that these emulsions are surprisingly stable (note pages 6 and 7).

Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Carlsson et al cited above, in view of Horrobin (4444755).

Carlsson et al teach a topical oil-in-water emulsion containing galactolipids as set forth above. Further, Carlsson et al teach the incorporation of dermatologic agents.

The reference does not teach the incorporation of instantly claimed anti-psoriasis agent.

Horrobin teaches the use of various essential fatty acids for the treatment of skin conditions such as psoriasis (see abstract, col. 1, line 18 through col. 3, line 39; col. 4, lines 25-46).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Carlsson et al and Horrobin. One

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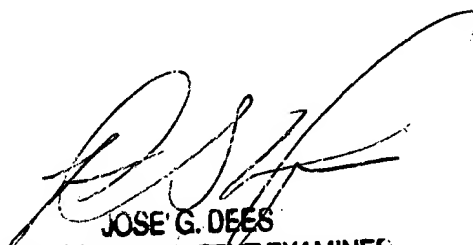
would be motivated to do so since the use of the claimed essential fatty acid as the are known for their effectiveness in the treatment of skin conditions such as psoriasis as evident from Horrobin. Alternately, as pointed out above, the use of the emulsions of Carlsson et al in the teachings of Horrobin would have been obvious to one of ordinary skill in the art since Carlsson et al teach that these emulsions are surprisingly stable (note pages 6 and 7).

Any inquiry concerning this communication from the examiner should be directed to Sharmila S. Gollamudi whose telephone number is (703) 305-2147. The examiner can be normally reached M-F from 7:30 am to 4:15pm.

If attempts to reach the examiner by the telephone are unsuccessful, the examiner's supervisor, Jose Dees, can be reached at (703) 308-4628. The fax number for this organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist, whose telephone number is (703) 308-1235.

SSG

  
JOSE G. DEES  
SUPERVISORY PATENT EXAMINER  
1616